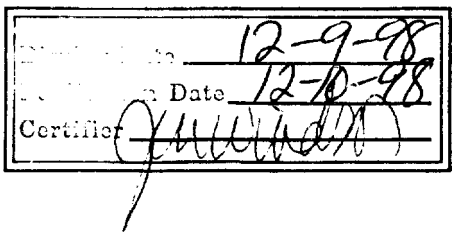
DMB



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98P-0221]

Zeneca, Inc.; Withdrawal of Approval of Portion of a New Drug Application Providing for a Formulation of Diprivan Injectable Emulsion Not Containing Disodium Edetate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of those portions of a new drug application (NDA) held by Zeneca, Inc., (Zeneca) for Diprivan (propofol) Injectable Emulsion that provide for a formulation not containing the antimicrobial additive disodium edetate.

EFFECTIVE PATE: (*Insert date of publication in the* **Federal Register.)**

FOR FURTHER INFORMATION CONTACT: Virginia G. Beakes, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: By citizen petition dated April 7, 1998 (Docket No. 98P–0221/CP1), Zeneca, 1800 Concord Pike, Wilmington, DE 19850, requested that FDA withdraw approval of those portions of NDA 19–627 that provide for a formulation of Diprivan Injectable Emulsion that does not contain the antimicrobial additive disodium edetate, stating that the company discontinued marketing the product because of potential contamination problems observed after approval of the NDA. Zeneca waived its opportunity for a hearing.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of those portions of **NDA** 19-627 that provide for a formulation of

Diprivan Injectable Emulsion that does not contain the antimicrobial additive disodium edetate is hereby withdrawn effective *(insert date of publication in the* **Federal Register).**

Dated: November 16, 1998

Janet Woodcock
Director
Center for Drug Evaluation
and Research

[FR Dec. 98-???? Filed ??-??-98; 8:45 am]

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